



Schering-Plough

June 13, 2002

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Integrated Therapeutics Group, Inc.  
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Rockville, Maryland 20852  
Telephone (301) 770-9524

Dockets Management Branch, HFA-305  
Food and Drug Administration  
5630 Fishers Lane  
Room 1060  
Rockville, MD 20852

**Re: Docket No. 00D-1542**

Draft Guidance for Industry on Electronic Records; Electronic Signatures, Time Stamps; Availability

To Whom it May Concern:

Schering Plough has reviewed the above cited draft guidance and we offer the following comments and/or observations for your consideration.

**General Comments**

While in theory the guidance provides for a sound implementation of time stamps, establishing this degree of control may not be value added for all types of systems. For example, having system security personnel fly around the world to conduct unannounced checks of computer clocks of personnel responsible for entering information from a paper form would not be as value added as conducting unannounced checks related to a clock that controls a particular processing time in a manufacturing facility.

The guidance does not address server-side time stamping vs. client-side time stamping. We believe server-side would be a preferred method where possible in order to overcome user overrides to client time setting.

**Section 2.1 Applicability**

The word "retrieve" should be clarified; i.e. does this refer to access of information from a database or archived source and is a timestamp needed for "read-only" functions?

**Section 5.1 Time Stamp Accuracy**

Please clarify what type of documentation would be required, as well as the training that would be required.

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## **Section 5.2 Systems Clock Security**

Internal clocks are set with the network clock upon connecting to an internal network. Devices such as laptops use this setting until the next network connection at which time the clock is resynchronized. Auditing of individual PCs is unnecessary and an added burden that will yield no discernable value. It is the operating system that dictates the ability to prevent system clock changes or not and system tests that look for out of sequence transactions is an adequate method of identifying anomalies.

## **Section 5.3 Time Zones**

With regard to the regulation, if the guidance supersedes the regulation, the regulation should be amended.

The guidance does not address the situation of using an offline application on a handheld device to create a record; after logging into the network with the handheld device the timestamp created would be different than when the information was actually entered into the handheld device.

## **Section 5.4 Expression of Date and Time**

We suggest that the example of the time provided include the time zone.

We appreciate the opportunity to comment on this draft guidance. If you have any questions, please contact me at (301) 770-9528

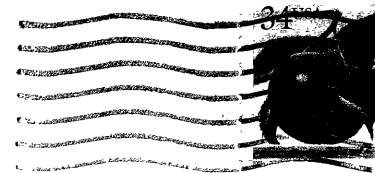
Sincerely,

A handwritten signature in black ink, appearing to read "Gretchen Trout". The signature is fluid and cursive, with the first name being more prominent.

Gretchen Trout  
Director, Regulatory Relations and Policy  
Worldwide Regulatory Affairs



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